

EXHIBIT B

1 OF 2

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS**

**IN RE: YASMIN AND YAZ (DROSPIRENONE)
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION**

3:09-md-02100-DRH-PMF
MDL No. 2100

This Document Relates to:

ALL CASES

DECLARATION OF DR. HENNING MOELLE.

FEDERAL REPUBLIC OF GERMANY
STATE OF HESSIA
FRANKFURT AM MAIN

1. I am a German attorney-at-law (*Rechtsanwalt*) practicing law in Frankfurt am Main (Germany). I have passed the German First Legal State Exam at the University of Passau in 1992 and the German Second Legal State Exam before the Higher Regional Court of Schleswig (Germany) in 1996. I have been awarded the degree of a *doctor iuris* from the University of Passau (Germany) and of a Master of Laws (LL.M.) from the University of Nottingham (UK). I was admitted to the legal bar of the courts of Frankfurt a.M. (Germany) in 1997. Since then, I have been practicing law as a German attorney (*Rechtsanwalt*) with a focus on national and trans-border litigation.
2. The facts stated in this Declaration are based upon my personal knowledge and my professional experience. If sworn as a witness, I would be competent to testify to the matters set forth herein.
3. I have been advised by Bayer Pharma AG (hereafter referred to as "Bayer") that Bayer is a defendant in the Yasmin/YAZ product liability litigation pending before courts in the U.S. Further, I have been advised by Bayer that the plaintiffs in this litigation have demanded that Bayer Pharma AG de-designate as confidential thirty documents produced by Bayer Pharma AG in the US Litigation pursuant to protective orders entered in the MDL, California, New Jersey, and Pennsylvania coordinated proceedings. I have also read plaintiffs' briefing on this topic, as well as the case management orders concerning the handling of confidential information in the MDL and other coordinated proceedings, including Case Management Order #7, entered in the MDL on December 18, 2009 (collectively "the Protective Order").
4. Bayer has asked me to opine whether under German data protection laws Bayer could lawfully de-designate the thirty documents at issue as demanded by plaintiffs in the US litigation.

5. As explained in more detail below, Bayer would risk violating German data protection laws if it de-designated twenty-eight of the thirty documents as demanded by the plaintiffs.¹ Under the German Federal Data Protection Act (BDSG), Bayer is constrained to processing and transferring information protected by the Act to the extent it is necessary for the purpose of the US litigation *and* if there were “no reason to assume” that data subjects have an overriding interest against the disclosure of their information (“balancing test”). This balancing test must take into account the principle of proportionality, the nature of the personal data, and the relevance of the personal data to the litigation.

6. It is generally possible to accommodate the interest of an individual in the protection of his or her personal data by making the disclosure of the personal data subject to imposing rigid confidentiality obligations upon the recipient of the data (*e.g.*, by way of confidentiality orders such as those entered in the MDL and other coordinated proceedings). Such confidentiality arrangements are then one further element to be considered in the context of the balancing test to be performed under the German Data Protection Act. Bayer has advised me that it has already made the thirty documents available for use in the litigation under the Protective Order, but only with the understanding that these documents would be designated confidential and that their confidentiality remained protected under the Protective Order. De-designating twenty-eight of the thirty documents would disrupt the balancing test factors applied in determining whether such documents could be made available in this litigation. Without a designation of the documents as confidential, the balancing test leads to the result that Bayer risks violating the German Data Protection Act. Violations of the German Data Protection Act are subject to prosecution as administrative or criminal offences.

The Legal Framework of Data Protection in Germany

7. Bayer AG faced a similar issue in 2003 when the New York Times sought to de-designate documents Bayer AG had produced pursuant to a protective order under similar circumstances in the Baycol litigation. In its opposition to that motion, Bayer AG submitted the Declarations of Prof. Spiros Simitis (Ex. A) and Prof. Wolfgang Däubler (Ex. B), leading experts on German and European Union data protection law, to explain the overarching structure of European and German constitutional and statutory data protection law and the application of that law. Professor Simitis is, among other things, the editor and co-author of the leading treatises on the Federal German Data Protection Law (*Kommentar zum Bundesdatenschutzgesetz*, 7th ed. 2011) and the European Data Protective Directive (*Kommentar zur EG-Datenschutzrichtlinie*, 1997). *See* Simitis Declaration (Ex. A). He is certainly the most highly reputed expert on data protection law in Germany. The principles outlined by Prof. Simitis and Prof. Däubler are still applicable today.

8. Under German laws, data protection is recognized as a fundamental right and high-ranking legal principle. Already in 1983, the German Federal Constitutional Court has held that the German Constitution (“*Grundgesetz*”) guarantees a “right to informational self-determination” (Decisions of the Federal Constitutional Court, Vol. 65, p. 1 *et seq.*). This is a constitutional right of every individual to determine the use of data that concern his or her person and includes the right to determine which personal data may be collected or used by whom for which purpose and under which conditions. As emphasized by the Constitutional

¹ Bayer has made copies of the 30 documents produced by Bayer Pharma AG available to me for review. Of these thirty documents, all but BSPYAZ34452 and BSPYAZ20389673 contain personal data within the sense of the Federal Data Protection Act (BDSG) and must therefore remain designated as confidential. I am not able to opine whether any of those 30 documents (including BSPYAZ34452 and BSPYAZ20389673) may be confidential for other reasons.

Court as well as by the German legislature, this right may be invoked by any individual whose personal data are collected, used, or processed in Germany, irrespective of the nationality, citizenship or domicile of the individual. *See* Simitis Declaration (Ex. A) at ¶ 9.

9. The scope of this constitutional right was codified and specified by the Federal Data Protection Act (“*Bundesdatenschutzgesetz*,” BDSG) in 1990. Accordingly, the BDSG serves to protect “*the individual against his right to privacy being impaired through the handling of personal data*” (§1(3) BDSG).

10. Following its enactment in 1990, the BDSG was later amended and reinforced to conform to the EU Data Protection Directive of 1995 (Directive 95/46/EC; *see* Simitis Declaration (Ex. A) at ¶ 11). The EU Directive requires the EU Member States “*to protect the fundamental rights and freedoms of natural persons, and in particular their right to privacy with respect to the processing of personal data*” (Art. 1(1) of the Directive). Amendments recently made to the BDSG in 2006 and 2009 have led to even further-reaching restrictions on the processing of personal data under German law when compared to the level of protection afforded under the EU Data Protection Directive. Thus, today the BDSG reflects the significance of data protection under the German Constitution and even goes beyond the level of protection afforded under the EU Data Protection Directive.

11. To achieve a maximum degree of data protection, the BDSG establishes the principle that the collection, processing and use of personal data is prohibited unless otherwise permitted:

“The collection, processing and use of personal data shall be lawful only if permitted or ordered by this Act or other law, or if the data subject has provided consent”
(§ 4(1) BDSG).

12. Violations of the BDSG are subject to prosecution as administrative or criminal offences and are punishable by fines or imprisonment of up to two years (§§43-44 BDSG). Also, the data subject can sue a party that collects, processes or uses his or her personal data in violation of the BDSG for damages (§7 BDSG) and may also seek an injunction against that party. As an ultimate means, data enforcement protection agencies may even shut down the business operations of companies violating data protection laws.

The Application of the BDSG to the Issues under Discussion

13. On page 10 of their brief, plaintiffs suggest that the BDSG is only of minor relevance and may not even apply to the matter at issue. This is not correct. The BDSG is the core element of German data protection legislation and applies to the issues under discussion here:

14. Plaintiffs appear to have been misguided by an incorrect and incomplete reading of the publication by *Schwartz* cited at footnote 26 of their brief (Exhibit G to plaintiffs’ brief). First, it should be noted that the *Schwartz* article was published in 1992. It thus does not account for the enactment of the EU Data Protection Directive of 1995 or for various other amendments which have been made to the BDSG to reinforce the protection of personal data since then. More importantly, however, Plaintiffs misconstrue the statements by *Schwartz* and cite them out of context. In his publication, *Schwartz* correctly states that the BDSG only applies to the extent that the data processor is not subject to any other data protection

laws which establish an even more rigid level of data protection in specific sectors (*see Schwartz* at page 139). Such sector-specific data protection laws exist, for example, in the area of telecommunications and financial services (*see Schwartz* at footnote 33 with further examples of sector-specific data protection laws). Insofar, the introduction of several sector-specific data protection laws (including state laws) has indeed limited the scope of the BDSG to the areas not covered by such sector-specific data protection laws. Yet, Plaintiffs utterly distort the interplay between the BDSG and sector-specific data protection laws by alleging that “*the scope of its influence has been questioned*” (page 10 of plaintiffs’ brief). The BDSG is the central piece of German data protection legislation. As federal law, it applies in all German states and absent any specific data protection laws dealing with the protection of data protection rights in the context of a US litigation, the BDSG also applies to the issues under discussion here.

Application of the BDSG to Bayer Pharma AG

15. Plaintiffs are misguided when they assume that the BDSG does not apply to Bayer Pharma AG because, in Plaintiffs’ view, Bayer Pharma AG allegedly engages in business activities in the USA through the US Bayer Defendants. The BDSG applies to the “controller” of personal data (§3(7) BDSG). As Bayer Pharma AG has collected, processed and transferred² the documents Bayer Pharma AG – and not any of the US Bayer Defendants – is the “controller” of the personal data and, hence, bound by the BDSG and exposed to sanctions in case of any violation of the BDSG. That Yasmin/YAZ are sold in the USA plays no role under the BDSG. The level of data protection afforded to data subjects under the BDSG does not, of course, depend on any business decisions by the “controller” of their personal data.

16. Bayer AG faced a similar issue in 2003 when the New York Times challenged the confidentiality of documents produced in connection with the Baycol litigation. Like Bayer Pharma AG, Bayer AG was affiliated with companies in the USA which were responsible for marketing the medication at issue in the USA. Nevertheless, Bayer AG received a letter from Dr. Heger, Head of the Department of International Law of Civil Procedure, Mutual Judicial Assistance and Arbitration at Germany’s Federal Ministry of Justice, making clear that vacating the protective order would create a state of affairs incompatible with the right of informational self-determination guaranteed by the BDSG and the German Constitution. Dr. Heger went on to state that publication of protected data would prevent Bayer AG from producing additional personal data in US proceedings. A certified English translation of Dr. Heger’s letter is attached as Exhibit C.

Application of the BDSG to the Documents at Issue

17. To account for the constitutional right of informational self-determination and to maximize the protection of personal data in accordance with the EU Data Protection Directive, the BDSG defines “*personal data*” broadly as

“any information concerning the personal or material circumstances of an identified or identifiable individual (‘data subject’)” (§3(1) BDSG).

² “Processing” of data within the sense of the BDSG includes any transfer of data, *see* §3(4) BDSG.

18. Thus, the BDSG applies to any data that concern an individual, irrespective of the nature of the data and in particular irrespective of how significant or sensitive the data may appear. *See* Simitis Declaration (Ex. A) at ¶¶ 17-21. “Personal data” for example include an individual’s address information (private and business address, phone number, email address, etc.), date of birth, sex, nationality or ethnic background as well as any and all information about family members, friendships, lifestyle, physical characteristics, religion, political beliefs, medical history, history of medication use, current health, education, employment, professional experience, memberships in sports clubs, professional associations or trade unions, financial status, etc. Also, the BDSG applies to all personal data irrespective of the circumstances under which the data have been generated or the purpose for which they have been collected. *Id.*

19. I have perused copies of the thirty documents whose de-designation plaintiffs seek. Twenty-eight of the thirty documents at issue contain personal data within the sense of the BDSG³. These twenty-eight documents include names, job titles, phone numbers, email addresses, or other personal data for literally hundreds of individuals, and thus concern the “personal or material circumstances of an identified or identifiable individual” (§3(1) BDSG). In my opinion, the twenty-eight documents must therefore be considered as personal data protected under the BDSG.

Lawfulness of the Processing and Transfer of Documents to the USA

20. As these twenty-eight documents and their processing (recording, storage, and transfer) for the purpose of the US litigation fall under the protection afforded by the BDSG, Bayer could only lawfully comply with the plaintiffs’ demand if their processing and transfer (i) occur with the consent of the data subjects, or (ii) are prescribed or permitted by the BDSG or by other law (*see* §4(1) BDSG).

Transfer of Personal Data to the USA

21. As a general matter, the BDSG, in accordance with the EU Data Protection Directive, prohibits a transfer of personal data to any jurisdiction outside the European Union and the European Economic Areas (EEA) that does not provide for rules on data protection functionally equivalent to the EU and therefore does not provide for “*an adequate level of data protection*” (§4b(2) BDSG). German and EU lawmakers have determined that US data privacy laws do not provide for an adequate level of data protection.

22. However, as an exception to the rule, the BDSG allows the transfer of personal data outside the European Union and the EEA to the extent that the transfer is necessary “*for the establishment, exercise or defence of legal claims*” (§ 4c(1)(4) BDSG). This condition is met with regard to the transfer of the documents to the USA for the purposes of the Yasmin/YAZ litigation.

23. On page 10 of their brief, plaintiffs indirectly refer to §4c(1)(4) BDSG by citing a decision from a US court. Plaintiffs however misinterpret the scope of this provision by suggesting that it provides for a general derogation from all other data protection requirements under the BDSG and that therefore this provision itself justifies the de-designation of the

³ Only BSPYAZ34452 and BSPYAZ20389673 do not contain personal data. I am not able to opine whether these two documents may be confidential for other reasons.

twenty-eight documents. This is not the case. §4c BDSG contains but a derogation from the specific prohibition under §4b BDSG to transfer personal data *to a non-EU country* without an adequate level of data protection (such as the US). Yet, §4c BDSG does not derogate the *general* BDSG requirements for the processing and transfer of personal data (whether within Germany, to another EU member state or to the USA). These general requirements continue to apply in parallel to §4c BDSG. In its leading treatise on the BDSG, Prof. Simitis describes this limited role of § 4c BDSG as follows⁴:

“A trans-boarder transfer is only admissible if the transfer of the relevant personal data is in general admissible under the applicable provisions of the BDSG (§§ 15(1), 16(1) and §§ 28 through 32). Any consideration about the application of §4c(1) and §4c(2) must therefore be preceded by confirming the requirements which the BDSG establishes for a transfer of data in general. If these requirements are not met, this excludes also and particularly any transfer to a third country.” (Simitis, *Kommentar zum Bundesdatenschutzgesetz*, 7th ed. 2011 at page 498).

24. Even if a transfer of the documents to the USA is not already excluded under §4b BDSG because such transfer occurred *“for the establishment, exercise or defence of legal claims”* (§ 4c(1)(4) BDSG), Bayer could therefore only lawfully transfer, process and use the documents with the data subject’s consent or if other provisions of the BDSG permit such transfer, processing and use.

Consent of the Data Subjects

25. Consent of a data subject to the processing and use of its personal data is effective only *“when based on the data subject’s free decision”* (§ 4a(1) BDSG).

26. Consent *“based on the data subject’s free decision”* means that the data subject must have a real opportunity to withhold his consent without suffering any disadvantage, or to withdraw his consent if he changes his mind later. As Prof. Däubler has pointed out, *“[a]n employer may not require an employee to give such consent.”* Däubler Declaration (Ex. B) at ¶ 10. A German employer has no right to request its employee to grant such consent or to not withdraw any consent given later. Any attempt by a German employer to exercise pressure upon its employee in this regard would invalidate any consent subsequently declared by the employee and would also be considered as a violation of the employer’s duties under the employment contract.

27. Plaintiffs’ suggestion that Bayer need not maintain these documents as confidential unless it has attempted to obtain consent is misguided. First, I understand that Bayer has produced many millions of pages of documents in this litigation. Obtaining consent - which must generally be given in writing (*see* §4a(1) BDSG) - from the thousands of individuals whose personal data appear in such documents prior to production in the US litigation appears highly impractical and would most likely have foreclosed production in the first instance. Even if confined to the twenty-eight documents at issue here, a relatively small number, obtaining such consent would require Bayer to contact hundreds of employees, former employees, and individuals who, I understand, have no current or past employment relationship with Bayer. Second, my understanding based on a review of plaintiffs’ briefs to the Court is that they intend to argue to the FDA that Bayer, including its employees, have in some way withheld required safety information from the FDA, or are responsible for US

⁴ My own translation of the German original text.

patients having unduly experienced side effects from the use of Yasmin/YAZ. Employees and other data subjects would be highly unlikely to give their consent under such circumstances. Third, even if a data subject should give its consent to the processing of its personal data, the data subject remains generally free to withdraw its consent later.

Justification under the BDSG or by Other Law

28. There are no legal provisions outside the BDSG which could permit the processing and transfer of the documents for the US litigation. Only German laws could determine if such processing or transfer is lawful under German laws.

29. The only legal provision under the BDSG that may permit Bayer to process and transfer the twenty-eight documents for the purpose of the US litigation is §28(1)(2) BDSG. §28(1)(2) BDSG justifies the collection, recording, alteration or transfer of personal data

“as far as necessary to safeguard legitimate interests of the controller and there is no reason to assume that the data subject has an overriding legitimate interest in ruling out the possibility of processing or use”.

30. §28(1)(2) BDSG thus requires Bayer (as the “controller” of the personal data) to confirm two conditions: (i) the processing and transfer of the twenty-eight documents as well as the scope of such processing and transfer (“as far as”) must be necessary to safeguard a legitimate interest of Bayer, and (ii) there must be no reason to assume an overriding legitimate interest of the data subjects against such processing or transfer (balancing test).

Balancing Bayer’s Legitimate Interest with the Rights and Interests of the Data Subjects

31. The BDSG recognises the establishment, exercise or defence of legal claims as “legitimate interest” of a data controller to process and use personal data. Bayer may however only process personal data and transfer the data to the USA as far as this is necessary to fulfil this interest and if there is no reason to assume that the data subjects have an overriding interest against such processing and transfer of their data (*see* §28(1)(2) BDSG). This is a balancing test. Bayer must weigh the interest in the processing and transfer of the personal data for the purpose of the US litigation against the constitutional rights of the data subjects. This balancing test must take into account the principle of proportionality, the nature of the personal data and the relevance of the personal data to the litigation.

32. As mentioned above, in some instances, the interest of an individual in the protection of his or her personal data may be accommodated by making the disclosure of the personal data subject to imposing rigid confidentiality obligations upon the recipient of the data. Any interest Bayer has in transferring the documents at issue for litigation has been fulfilled by Bayer’s production of those documents with the confidentiality designation and relying on the protection of the confidentiality of the documents under the Protective Order. I am unaware of any additional legitimate interest which Bayer (as the responsible “data processor”) could pursue by removing the confidentiality designation on these documents, such that they could be disclosed to individuals or groups outside the US litigation⁵. In particular, the interest of

⁵ At footnote 29 of their brief, plaintiffs refer to §4c BDSG and to §40(4) BDSG (see plaintiffs reference to “40(4)”) suggesting that these provisions alone justified the de-designation of the documents. This is not correct. As to §4c BDSG it must be reminded that §4c BDSG only creates an exception to the prohibition under §4b BDSG to transfer personal data to non-EU countries without an adequate level of data protection. §4c BDSG does thus not itself justify the processing and transfer; the general requirements under §28 BDSG must be met

Ms Deitrick to exercise her individual petition right to the FDA cannot constitute a genuine interest of *Bayer* (the data controller) as it is however required under § 28(1)(2) BDSG.

33. Considering the absence of a legitimate interest in the disclosure of this information without a confidentiality designation, the balancing test suggests that *Bayer* would violate German data protection laws if it disclosed the documents at issue without protection by the confidentiality designation and the Protective Order respectively.

34. *First*, it must be noted that the individuals to whom the documents relate are foreign to the US litigation and have no direct genuine interest in the disclosure of their personal data.

35. *Second*, if the twenty-eight documents were de-designated for petitioning the FDA, the data subjects would run the risk that any third party to which their personal data is disclosed or may otherwise become known in the course of the FDA hearing could later process, transfer or use their personal data for any other purpose without obeying the limits set by German data protection law. US residents and US government institutions are of course not themselves subject to German data protection law. The individuals thus clearly have an overriding interest within the sense of §28(1)(2) BDSG against the de-designation of the twenty-eight documents to prevent them from any disclosure outside the US litigation.

36. *Third*, German courts as well as the German legislator have expressed the high importance which must be placed to the protection of an individual's personal data and to the need to strictly limit their use (see above at paragraphs 8 through 12). If the documents were de-designated, there would no longer be a sufficiently effective safeguard in place to ensure that the personal data must not be used for any purpose other than the "legitimate purpose" (namely the US litigation) for which they had originally been processed and transferred in accordance with the German Data Protection Act. Unless the Protective Order and the designation of the documents as confidential continues to prevent the documents from being used for purposes other than the US litigation, *Bayer* (or any other German company in a similar situation) would risk sanctions for violation of the BDSG. With regard to the request by the *New York Times* to have documents de-designated for use outside the *Baycol* litigation, Prof. Simitis summarized the importance to maintain the designation of personal data and their protection under the protective order in the *Baycol* litigation as follows:

"Modifications of the order that would lead to a processing clearly contravening these rules by broadening the access to the data and permitting further uses definitely rejected on constitutional grounds by the Federal Data Protection Act, deprives the transfer from its legal basis, renders the transmission illicit and exposes the original

(see above at ¶¶ 23, 24). Also, the exercise of individual petition rights is not "an immediate matter of public concern" within the sense of the BDSG. As to plaintiffs' reference to "40(4)", it first needs to be noted that §40(4) BDSG no longer exists under the BDSG as in force today. More importantly, however, plaintiffs err when describing §40 BDSG (as in force today or at the time when it still contained §40(4) BDSG) as a provision allowing access to personal data collected by research institutes. §40(1) BDSG establishes that personal data which was collected for scientific purposes must be used for scientific purposes only and not for any other purpose. It thus reiterates the limitations to the use of personal data rather than to extend their accessibility. Whether or not such data may be transferred (made accessible) to any third party at all, is not regulated by §40 BDSG but remains subject to the other pertinent provisions of the BDSG, including §28 BDSG. Beyond that, §40(3) BDSG merely justifies the publication of personal data in the interest of academic research if and to the extent that this is indispensable to publish the results of a research work (e.g. a scientific publication about the vita of a person playing an important role in contemporary history). This is clearly not at issue here.

data controllers to the sanctions foreseen in § 7⁶ and § 43(2) No 1.⁷ of the Federal Data Protection Act.” (Simitis Declaration (Ex. A) at ¶ 46)

This equally applies to plaintiffs’ request for de-designation of the documents in the Yasmin/YAZ litigation.

37. Summarizing, under German data protection laws and in consideration of the individual’s underlying constitutional rights to informational self-determination, Bayer could only lawfully process and transfer the documents at issue for the purpose of the US litigation after conducting the balancing test. Upon conducting this test prior to the processing and transfer of the data, Bayer determined that processing and transfer was justified in this limited context and with the confidentiality safeguards under the Protective Order which sanction the disclosure and use of the data to any third party or for any purposes not strictly related to the purpose for which Bayer could legitimately process and transfer the data to the US. However, if the twenty-eight documents at issue were de-designated, the conditions for process and transfer would not be met. Bayer would risk violating German data protection laws if the documents were now de-designated as demanded by the plaintiffs. Bayer and its officers respectively would then risk prosecution under German data protection laws.

38. I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.


Dr. Henning Moelle

Executed on 7 November 2011
In Frankfurt am Main, Germany

⁶ § 7 BDSG establishes the data subject’s right to seek civil damages from the data controller for violation of its privacy rights.

⁷ § 43 BDSG subjects the data controller to criminal sanctions in case of violation of the BDSG.